Standards Working Group Meeting Procedures

The Scientific and Medical Accountability Working Group ("SMAS WG" or the "Working Group") is committed to an open and public process. While Proposition 71 provides that the SMAS WG is not bound by formal State meeting and records requirements, the business of this Working Group will be conducted in a spirit of openness and participation so that the recommendations of the Working Group reflect both the expertise of its members and the input of the people of California.

The SMAS WG does not make final decisions on matters, but will provide the ICOC with recommendations on standards for CIRM funded research and clinical trials, and make recommendations on oversight of CIRM funded research to ensure compliance with the standards. The procedures outlined here are intended to apply primarily to the standard setting activities of the SMAS WG. As the SMAS WG gains operating experience and the range of its oversight activities becomes better defined, modifications to these procedures may be required. Proposed changes to these procedures will be proposed to, discussed by and, if appropriate, acted upon by the ICOC in due course.

Through the following steps, which will engage the public at all milestones, the SMAS WG will gather and analyze information, reach decision points on proposed standards, prepare draft and final recommendations and forward these recommendations to the ICOC:

- Give public notice of meetings in a timely manner and post proposed meeting agendas (all materials will be made available to the public at the same time as they are made available to the Working Group members);
- Hold public meetings and provide public comment periods during each meeting;
- Hold meetings which members of the public will be encouraged to attend and at which they may comment on draft findings and recommendations;
- Take public votes of the Working Group members on decisions and recommendations to the ICOC (no public vote will be taken by the Working Group on a decision or recommendation to the ICOC prior to providing opportunity for public comment);
- Post publicly the Working Group's final recommendations and minority and individual opinions to be forwarded to the ICOC on matters that emerge out of the foregoing process; and
- Meet in Confidential Session only if needed, e.g., to review a complaint regarding an investigator's or institution's compliance with medical or ethical standards adopted by the ICOC, with any final action to be taken in a public meeting.

Members of the SMAS Working Group may participate in meetings from any number of locations through telephone or other available connection so long as all participants can hear all other participants, and the public can listen and participate either through a telephone conference link or at a meeting site where the proceedings may be heard directly and through a loud speaker.The public will be invited to comment at meetings of the Working Group and, in addition, it is the goal of the CIRM to configure its website to allow the public to post comments.

The SMAS WG will be assisted by staff, a subset of the Working Group members, or an individual Working Group member in preparing drafts. Preliminary draft text may be reviewed and commented upon by some or all of the Working Group members in preparation for public consideration of the draft. This portion of the process will generally not be undertaken in a public environment. The process of preparing draft reports (including minority reports), and communications among persons designated to prepare drafts or among the members of the SMAS WG will not be considered meetings of the SMAS WG. Once a draft or drafts have been prepared, however, the SMAS WG will conduct a public meeting to obtain comments from members of the public.

All recommendations from the SMAS WG are subject to review by the ICOC in a public meeting. Prior to adopting the standards recommended by the SMAS WG as formal CIRM regulations, the ICOC will follow any and all additional State public review and comment requirements.